

**Del Mar Reynolds Medical Ltd.**  
**Special 510(k)**  
**510(k) Summary**  
Voyager 12

Revised October 18, 2006

**1. Submitter Information**

NOV - 3 2006

Name: Del Mar Reynolds Medical Ltd.

Address:

1 Harforde Court  
John Tate Road  
Hertford, Herts SG13 7NW  
ENGLAND

Telephone Number: +44-1992-507700

Contact Person:

Dr. George Myers (Official Correspondent)

Medsys Inc.

377 Route 17 S

Hasbrouck Heights, NJ 07604

Telephone 201-727-1703

Fax 201-727-1708

Date Prepared: 19 October 2006

**2. Name of Device**

Trade Name: Voyager 12

Common Name: 12-Lead Digital Electrocardiograph

Classification name: Electrocardiograph

**3. Equivalent legally-marketed devices.**

- ☐ Del Mar Reynolds Medical CardioDirect 12I, K024283
- ☐ Burdick Eclipse 4, K946281

**4. Description**

Voyager 12 is a 12-lead digital electrocardiograph with interpretation of the electrocardiogram. Voyager 12 is a portable, self-contained unit with an internal printer. It permits either manual or automatic interpretation of electrocardiograms.

**5. Intended Use**

Voyager 12 is intended to be used record and interpret an electrocardiogram of a patient. This includes a resting electrocardiogram and a rhythm electrocardiogram.

**6. Performance Data**

**(a) Non-clinical tests**

1. IEC 60601-1
2. IEC 60601-2-25
3. IEC 60601-2-51
4. Validation tests
5. IEC 60601-1-2

**(b) Clinical tests**

Clinical tests are not necessary since Voyager 12 uses the same technology as the predicate device.

**(c) Conclusions**

Voyager 12 is equivalent in safety and efficacy to the legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV - 3 2006

Medsys, Inc.  
c/o Mr. George Myers  
President  
377 Route 17 S  
Hasbrouck Heights, NJ

Re: K062469

Trade Name: Voyage 12 ECG Interpretation Cart  
Regulation Number: 21 CFR 870.2340  
Regulation Name: Electrocardiograph  
Regulatory Class: Class II  
Product Code: DPS  
Dated: October 24, 2006  
Received: October 25, 2006

Dear Mr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Bram D. Zuckerman for".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K062469

Device Name: Voyager 12

**Indications for Use:**

The use of Voyager 12 is indicated when it is desired to record and interpret an electrocardiogram of a patient. This includes a resting electrocardiogram and a rhythm electrocardiogram,

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

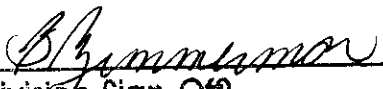
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(Posted November 13, 2003)

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Center for Devices and Radiological

  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K062469